

此为证书 CN17/20703 译本

下述组织

斯派曼电子技术 (苏州工业园区) 有限公司

中国江苏省苏州工业园区金江路 86 号

的管理体系已经过审核，并被证明符合下述要求

ISO 13485:2016

EN ISO 13485:2016

所涉及的活动范围覆盖

用于 X 射线成像系统的高压发生器的设计和生产

该证书的有效期自 2022 年 08 月 05 日 至 2025 年 08 月 04 日 并须经过符合要求的监督审核保持有效

版本号 4. 初始注册日期 2017 年 06 月 13 日.

签署



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Certificate CN17/20703

The management system of

Spellman High Voltage Electronics (Suzhou Industrial Park) Co., Ltd.

No. 86 Jinjiang Road, Suzhou Industrial Park, Suzhou City, Jiangsu Province, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016

EN ISO 13485:2016

For the following activities

Design and Manufacture of High Voltage Generator used for X-Ray Imaging System

This certificate is valid from 05 August 2022 until 04 August 2025 and remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 13 June 2017.

Authorised by



SGS United Kingdom Ltd

Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK

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